

**Summary of the
Accrediting Authority Committee Teleconference
December 10, 1996**

The National Environmental Laboratory Accreditation Conference (NELAC) Accrediting Authority Committee met by teleconference from 1:00 to 4:00 p.m. Eastern Standard Time (EST) on Tuesday, December 10, 1996. The meeting was led by Committee Chair, Mr. John Anderson of the State of Illinois Environmental Protection Agency (IL-EPA). A list of action items is given in Attachment A. A list of Committee members/invited guests is given in Attachment B. A copy of the teleconference agenda is given in Attachment C.

INTRODUCTION

The purpose of the teleconference was to continue to discuss the updated version of Chapter 6. The following items were discussed:

- Action Items Identified in the Minutes of the November 26, 1996, Teleconference -- Minutes had been prepared and reviewed by Mr. Anderson but had not been approved by Ms. Jeanne Mourrain, NELAC Director, so they were not distributed to the Committee at this time. Each action item was identified as a revision in the current draft so action items were discussed during the systematic review of Revision 5, Chapter 6.
- Review of the Updated Version (Revision 5) of Chapter 6 -- The Committee systematically reviewed section by section Revision 5 of Chapter 6.

The Committee discussed the Second NELAC Interim Meeting to be held at the Bethesda Hyatt Regency (301) 657-1234, Bethesda, MD, February 3-5, 1996. Ms. Emily Williams will mail brochures for this meeting, NELAC Ii, to Mr. Anderson for distribution to the Committee.

SYSTEMATIC REVIEW OF CHAPTER 6

6.1 -- Introduction

The Committee approved the editorial addition of "National Environmental Laboratory Accreditation Conference (NELAC)."

6.2 -- General Provisions

(d)

The Committee approved deleting the term “extend,” because this term was not used in other sections of Chapter 6, and approved changing the section to the following: “the authority for granting, maintaining, suspending or revoking NELAP accreditation.”

(g)

The Committee approved the section as revised with the addition of “or renewal.”

(h)

The Committee extensively discussed the two-year waiting period for a laboratory to obtain accreditation from another accrediting authority if the laboratory is located in a state that does not have a NELAP-recognized accrediting authority. The Committee concurred that the two-year waiting period was too long and agreed to delete “Starting two years from the date that the NELAP is officially implemented” from Section (h). However, upon further discussion, the Committee agreed that with the deletion of the clause in (h), issues formerly addressed in Section (h) were already addressed in Section (g), so the entirety of Section (h) was deleted/merged with Section (g).

(i)

The Committee agreed that all government laboratories will seek accreditation from their own state accrediting authority, and changed this section to read as follows: “Government laboratories not an organizational unit with the department or agency in which the accrediting authority is located shall apply for NELAP accreditation through their home state accrediting authority.” The individual representing the USEPA Committee member at this Committee meeting concurred in this approach to government laboratory accreditation.

(j)

The question of an accrediting authority’s accreditation of its own laboratory was discussed at length. The Committee proposed that a state accrediting authority should be allowed to select another state accrediting authority to accredit laboratories that are organizational units of its own department or agency. The Committee considered that reciprocal agreements, such as Memoranda of Understanding (MOUs) or Memoranda of Reciprocal Agreements (MRAs) could serve as a vehicle for “sister” states to accredit one another’s laboratories. When the National Environmental Laboratory Accreditation Program (NELAP) is fully implemented, there will not be a USEPA program to accredit laboratories (such as the existing primacy program in National Exposure Research Laboratory [NERL] that accredits drinking water labs); therefore, other accrediting authorities will have to serve as the accreditors. Mr. Anderson will raise this issue with EPA counsel and ask for comments. This section will be modified to read as follows: “Government laboratories that are organizational units of the same department or agency in which the state accrediting authority is located, or have other institutional conflicts-of-interest, shall apply for NELAP accreditation from any other NELAP-recognized accrediting authority.”

(l)

The Committee approved changing “scope” to “fields of testing” to be consistent with other NELAC chapters.

6.3.1 -- Written Application for NELAP Recognition

(a)

The Committee approved the editorial change of deleting “United States Environmental Protection Agency” and maintaining USEPA.

(g)

The Committee approved changing “this Chapter” to “the NELAC standards” for consistency in requirements.

6.3.3 -- Application Technical Review by a NELAP Assessment Team

(a)(4)

The Committee approved the additions in this section to clarify the audit cycle.

(b)

The Committee approved the editorial change from “National Environmental Laboratory Accreditation Conference” to “NELAC.”

(d)(19)

The Committee approved deleting “and this Chapter” to indicate that “arrangements . . . are carried out in compliance with the NELAC standards.”

(d)(19)(B)

The Committee agreed to delete “this Chapter” and add “the NELAC standards” for consistency.

(d)(19)(C)

The Committee approved changes to this section to ensure that subcontractors are not directly involved with professional laboratory associations as discussed in the December 4, 1996, teleconference.

(d)(20)

The Committee agreed to change “performance evaluation sample” to “proficiency testing” to be consistent with terminology used in Chapter 6 and in other NELAC chapters.

(e) (f) (g) and (h)

The Committee discussed these sections relative to approval/denial issues for NELAP recognition. The Committee agreed that the role of the NELAP assessment team was to gather information about the accrediting authority and to recommend to the NELAP Director approval/denial of recognition, rather than to approve or deny the recognition. The appropriate terminology for revision of the sections to address these issues was discussed, and a suggestion was made to incorporate terminology such as “completes the review and denotes no deficiencies.” Mr. Anderson and Ms. Jeri Long will rewrite these sections to address approval/denial or revocation of NELAP recognition.

(i)

The Committee approved using “initial” application for clarification.

(k)

The Committee concurred with the revision as written, except for the use of the term “approval.” A suggestion was made that “approval” be changed to “acceptance.”

Section 6.4 -- On-Site Audit of the Accrediting Authority

(a)

The Committee approved this section as revised to clearly define the four-year cycle of on-site audits.

(b)

The Committee approved the revision of this section to delete “routine” audits and allow the NELAP assessment team to schedule unannounced audits.

(c)

The Committee approved the change of “this Chapter” to “NELAC standards” for consistency in the Chapter.

Section 6.4.1 -- Scheduling the On-Site Audits

The Committee approved deleting “initial or routine” consistent with Section 6.4(b) to allow unannounced on-site audits as discussed in the December 4, 1996, teleconference.

(a)

The Committee approved including the reference to Section 6.4(a) for scheduling an on-site audit.

6.4.2 -- Conducting the On-Site Audit

(a)

The Committee approved the change from “this Chapter” to “NELAC standards” to maintain consistency in the chapter.

(a)(3)

The Committee extensively discussed the right of the NELAP assessment team to accompany an accrediting authority's assessors on an on-site audit of a laboratory. Because of questions that were raised about the terminology "option of the NELAP Director," Mr. Anderson reminded the Committee that Ms. Mourrain considered that, because of resource issues, it was unlikely that the NELAP assessment team would accompany assessors on an on-site audit. Mr. Anderson acknowledged that in order for an accrediting authority to be recognized by NELAP, specific requirements must be met; observance of an accrediting authority's assessors was incidental relative to the other criteria. Concerns that the laboratory would be placed in a sensitive position with the members of the NELAP assessment team accompanying the assessor(s) were raised. Therefore, the Committee suggested adding language stating that the NELAP assessment team would not contribute to the assessment of the laboratory. Mr. Anderson will modify this section to read as follows: "observing, at the recommendation of the NELAP assessment team and with the approval of the NELAP Director, an accrediting authority's laboratory assessor(s) conducting an on-site audit of a laboratory seeking initial or renewal NELAP accreditation, but shall not participate in the laboratory assessment."

(c)

The Committee approved changing "this Chapter" to "NELAC standards" for consistency in the chapter.

(d)

The Committee approved the additions as written to allow the NELAP assessment team to talk with personnel in the accrediting authority and with personnel in laboratories accredited by the accrediting authority. Discussions about this issue were raised in the December 4, 1996, teleconference relative to compliance with ISO Guide 58 requirements.

Section 6.4.3 -- On-Site Audit Reports

(a)

The Committee approved all changes in this section. Primarily, these changes involved modifying terminology for consistency in the chapter and with other NELAC chapters. These changes included changing "scope of" to "fields of testing" and changing "this Chapter" to "the NELAC standards."

(c)

The Committee approved deleting "or this Chapter" and pluralizing "standard" to "NELAC standards."

(d)(5)

The Committee continued to discuss the time required for legislative and regulatory processes to be completed because the length of time differs from state to state. Some states can facilitate

changes within one year, but the average time required for legislative changes was estimated to vary between three and five years. On the basis of this information, the Committee considered that the two-year limitation required in this section might be too restrictive. A suggestion was made to change “the NELAP assessment team shall recommend to the NELAP Director” to “the NELAP assessment team may recommend to the NELAP Director.” This issue was not resolved, and Mr. Anderson will add it to the agenda for the NELAC Second Interim Meeting.

(e)

The Committee approved the revision to this section to require that a plan of corrective action be submitted within 30 days of receipt of the on-site audit report.

(g)(3)

The Committee suggested that “interim” be deleted from this section. Mr. Anderson will review the section and make changes, as appropriate.

(h)

The Committee continued to discuss at length the issue of funding (travel, accommodations, and meals) for the NELAP assessment team to perform on-site audits and raised the question of the source of funding (NELAP versus the accrediting authority). Mr. Anderson and Ms. Long will rewrite the section to address funding issues specifically related to on-site audits of an accrediting authority by the NELAP assessment team.

Section 6.5 -- NELAP Assessment Team Recommendations to the NELAP Director

(d) and (e)

The Committee questioned the difference in the 15-day and 20-day time periods specified in Sections (d) and (e), respectively. Mr. Anderson indicated that the 20 days specified in Section (e) allowed the NELAP director 5 days to respond to the accrediting authority. Because the Committee found the differences in time requirements confusing, Mr. Anderson will delete Section (d) and include only terminology in Section (e) in the new revision of Chapter 6. The Committee agreed to these changes.

Section 6.6 -- Certificate of Recognition to the Accrediting Authority

(a)

The Committee agreed to delete the term “interim.”

(b)(3)

The Committee agreed that this section requires the date on the certificate to specify the date of the most recent on-site audit.

(b)(4)

The Committee agreed that “either” should be deleted and the section should read as follows: “granting NELAP recognition.”

(b)(7)

The Committee agreed that terminology in this section be changed to “a statement that the accrediting authority is in compliance with NELAC standards” to be consistent with Section 6.3.3(d)(19).

Section 6.7 -- Requirements of the NELAP

(b)

The Committee approved the revision to specify a record retention requirement of a minimum of 10 years.

Section 6.7.1 -- NELAP Assessment Team

(a)

Mr. Anderson indicated that the reference to Section 6.3.3(d)(4) was erroneous and the citation would be corrected.

(b) and (c)

The Committee discussed at length Sections (b) and (c) relative to the number of members of the NELAP assessment team and the rationale for designating that the team would be comprised of two members. Mr. Anderson indicated that the EPA had limited the NELAP assessment team to two individuals on the basis of funding constraints. Because of the diversity and complexity of the NELAP program relative to fields of testing, the Committee discussed the possibility that two team members may not be able to provide the backgrounds of technical expertise required, but the Committee members disagreed on the number of members that would be appropriate on this team. When Mr. Anderson reviewed the EPA’s concept that the team would be comprised of two members, one member from the EPA and a second member from a NELAP-recognized accrediting authority, the Committee raised the question of including a member of a third-party (subcontractor) such as the American Association for Laboratory Accreditation (A2LA) on the NELAP assessment team. However, there was consensus that the states would maintain their status as accrediting authority, even if a state (accrediting authority) entered into contractual agreements with a third-party organization for evaluation of laboratories. Mr. Anderson suggested that commercial laboratories approach the Environmental Laboratory Advisory Board (ELAB) and propose that the NELAP assessment team be expanded beyond two members. Mr. Anderson will rewrite the section to include the following: “at least one member from the USEPA and at least one member from a NELAP-recognized accrediting authority.”

(d) and (e)

The Committee discussed the credentials sought in individuals for the NELAP assessment team. It was suggested these individuals be required to have more education and experience than an accrediting authority's on-site assessors. Because the NELAP assessment team will be evaluating an accrediting authority, the Committee considered that it would be advantageous to select individuals with both administrative and technical expertise. However, the Committee agreed that the availability of such individuals may be limited. Mr. Anderson did not agree that different qualifications were necessary and applicable for accrediting authority assessors vis-a-vis the NELAP assessment team. Mr. Jim Meyer will draft a proposal to rewrite Sections (d) and (e) to address educational and training requirements for members of the NELAP assessment team, using wording to quantitatively address qualifications and selection criteria, such as Quality Systems or Lead Assessor training. Mr. Anderson suggested that the use of terms like "administrative experience" are not definitive and should not be acceptable. The Committee questioned the availability of Chapter 3 and its coverage of these issues. The revised wording to be prepared by Mr. Meyer will be included in Revision 6. Mr. Anderson suggested that this issue be raised at the Second NELAC Interim Meeting.

Section 6.8 -- Appealing Decision to Deny or Revoke NELAP Recognition

The Committee raised the question of an appeal by an accrediting authority of the selection of the NELAP assessment team on the basis of conflict-of-interest issues. This was not addressed in Chapter 6, and the Committee agreed that these appeals should be handled informally by the NELAP Director prior to the assessment team beginning its work.

(a)

The Committee approved this section as written.

(b)

The Committee discussed NELAC's role of writing standards, rather than serving as an appeal board or getting involved in any other way with the appeal process. NELAC delineates criteria, such as knowledge of laboratory accreditation issues, and has no direct involvement in laboratory accreditation programs. Thus, the Committee concurred that the NELAP Director select and appoint the members of the Appeal Board.

6.9(c)

The Committee discussed the meaning of "funding structure" and suggested that this section be revised to read as follows: "funding structure' means the fees charged to the laboratories applying for NELAP accreditation, the mechanism to collect laboratory accreditation fees, the schedule of payment of laboratory accreditation fees and the procedures for the accrediting authority to determine laboratory accreditation fees."

Section 6.2(c) -- Unconditional Reciprocity

The issue of unconditional reciprocity had not been resolved in earlier teleconferences and was reserved for discussion at this time. Ms. Aurora Shields and Mr. Anderson both provided to the Committee revisions of this section. A comment was made that the revisions prepared by Ms. Shields and Mr. Anderson did not differ significantly. However, Ms. Shields suggested that the section she prepared allowed an accrediting authority more flexibility in the documentation required from a laboratory requesting reciprocity. The Committee discussed reciprocity from the standpoint that reciprocity excluded a laboratory from having to provide any information other than the laboratory's certificate for a particular field of testing, and considered that reciprocity was defined as mutual acceptance. A comment was made that because NELAP will be a voluntary program, States that cannot adopt reciprocity should not become recognized by NELAP. Another comment suggested that a state has the option of rejecting poor or objectionable data independent of NELAP recognition and reciprocity. The issue of unconditional reciprocity was not resolved. Mr. Anderson indicated that this issue will have to be resolved and suggested the possibility of taking a vote by voting members of the Committee at the next teleconference. Another option is to defer final resolution of this issue until the Second NELAC Interim Meeting set for February 3-5, 1997.

CONCLUSION

Mr. Anderson concluded the teleconference by indicating that revisions would be made in the existing document, and Revision 6 of Chapter 6 would be distributed to the Committee for review before the next teleconference.

NEXT TELECONFERENCE

The next teleconference is scheduled for Wednesday, December 18, 1996 from 1:00 to 3:00 p.m EST. At that teleconference the Committee must take action on a final draft to be presented at the February 3-5 Interim Meeting. We have committed to NELAP officials that such a draft will be approved by the Accrediting Authority Committee at its December 18th meeting.

ACTION ITEMS
Accrediting Authority Committee Teleconference
December 10, 1996

Item No.	Action	Date Completed
1	Ms. Williams will mail a hard copy of the Second NELAC Interim Meeting brochure to Mr. Anderson.	December 11, 1996
2	Mr. Anderson and Ms. Long will change terminology in Section 6.2(d) to “granting, maintaining, suspending or revoking.”	December 13, 1996
3	Mr. Anderson and Ms. Long will add terminology to include renewal of NELAP recognition to Section 6.2(g) and incorporate Section 6.2(h) into this section.	December 13, 1996
4	Mr. Anderson and Ms. Long will rewrite Section 6.2(i) to indicate that “government” laboratories should apply for NELAP accreditation through their home state accrediting authority.	December 13, 1996
5	Mr. Anderson and Ms. Long will rewrite Section 6.2 (j) to indicate that laboratories within the jurisdiction of a state accrediting authority, or laboratories that have institutional conflict-of-interest issues, will seek accreditation through another NELAP-recognized accrediting authority.	December 13, 1996
6	Mr. Anderson will discuss with the EPA how NELAP will address the primacy requirement of the EPA’s Drinking Water Program.	
7	Mr. Anderson and Ms. Long will change the terminology in Section 6.3.3(d)(20) from “performance evaluation sample” to “proficiency testing.”	December 13, 1996
8	Mr. Anderson and Ms. Long will rewrite Sections 6.3.3(e), (f), (g), and (h) to address approval/denial of NELAP recognition relative to an accrediting authority’s performance on an on-site audit.	December 13, 1996

ACTION ITEMS
Accrediting Authority Committee Teleconference
December 10, 1996

Item No.	Action	Date Completed
9	Mr. Anderson will rewrite Section 6.3.3(k) to include appropriate terminology (such as “acceptance”) for an accrediting authority’s satisfactory performance on the technical (paper) audit.	December 13, 1996
10	Mr. Anderson and Ms. Long will modify Section 6.4.2(a)(3) to indicate that the NELAP assessment team may observe an on-site assessment of an accrediting authority with the approval of the NELAP Director.	December 13, 1996
11	The amount of time required for states to legislate changes in laboratory accreditation programs was unclear to the Committee. Mr. Anderson and Ms. Long will use the term “may” instead of “shall” to address the uncertain time requirements covered in Section 6.4.3(d)(5). Mr. Anderson will add this issue to the agenda for the NELAC Second Interim Meeting.	December 13, 1996
12	Mr. Anderson will review Section 6.4.3(g)(3) for the appropriateness of the term “interim.”	December 13, 1996
13	Mr. Anderson and Ms. Long will revise Section 6.4.3(h) to clarify that EPA will provide funding for travel, accommodations, and meals associated with the NELAP assessment team’s expenses for the on-site audit only.	December 13, 1996
14	Mr. Anderson will delete Section 6.5(d) and incorporate this section in Section 6.5(e) to indicate that the NELAP Director will respond to an accrediting authority within 20 days of receipt of the NELAP assessment team’s recommendations.	December 13, 1996
15	Mr. Anderson will delete the term “either” from Section 6.6(b)(4).	December 13, 1996

ACTION ITEMS
Accrediting Authority Committee Teleconference
December 10, 1996

Item No.	Action	Date Completed
16	Mr. Anderson and Ms. Long will rewrite Section 6.6(b)(7) to use the terminology “the accrediting authority is in compliance with NELAC standards” to be consistent with terminology used in Section 6.3.3(d)(19).	December 13, 1996
17	Mr. Anderson will check the citation in Section 6.7.1(a) for correctness.	December 13, 1996
18	Mr. Anderson will rewrite Sections 6.7.1(b) and (c), changing terminology to “at least one member” to indicate the Committee’s concern that the NELAP assessment team should be comprised of more than two individuals. Mr. Anderson will add this item to the agenda for the NELAC Second Interim Meeting.	December 13, 1996
19	Mr. Meyer will rewrite Sections 6.7.1(d) and (e) to address credentials (that include specifics about the education, experience, and training) for the NELAP assessment team members. Mr. Anderson will add this issue to the agenda for the NELAC Second Interim Meeting.	December 13, 1996
20	Mr. Anderson will rewrite Section 6.9(c) to include the terminology “laboratories applying for NELAP accreditation.”.	December 13, 1996
21	The Committee will continue to discuss “unconditional reciprocity,” Section 6.2(c), relative to revisions provided by Ms. Shields and Mr. Anderson at the next teleconference in order to resolve the issue at that time.	

LIST OF COMMITTEE/TELECONFERENCE PARTICIPANTS
Accrediting Authority Committee Teleconference
December 10, 1996

Name	Affiliation	Phone/Fax/E-mail
John Anderson, Chair	Illinois EPA, Division of Laboratories	Tel: 217-782-6455 Fax: 217-524-0944 E-mail: epa6103@epa.state.il.us
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Ed Glick (Substituting for Mary Ann Feige)	USEPA, Cincinnati (Invited Guest)	Tel: 513-569-7944 Fax: 513-569-7191 E-mail: feige.maryann@epamail.epa.gov
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Emily Williams (Support Contractor)	Research Triangle Institute	Tel: 919-541-6217 Fax: 919-541-5929 E-mail: emily@rti.org
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LIST OF COMMITTEE MEMBERS/TELECONFERENCE PARTICIPANTS

Accrediting Authority Committee Teleconference

December 10, 1996

Invited Guests:

Name	Affiliation	Phone/Fax/E-mail
Mary Ann Feige (Absent)		
Roxanne Robinson (Absent)	A2LA (Invited Guest)	Tel: 301-670-1377 Fax: 301-869-1495 E-mail: rrobinson@a2la.org

AGENDA
Accrediting Authority Committee Teleconference
December 10, 1996

1:00 p.m. Eastern Standard Time

Review minutes of 12/04/96
Committee Meeting and Status of
Assignments from that meeting
(Minutes not yet distributed).

Discuss and hopefully approve wording
changes authorized during our 12/04/96
meeting. These wording changes are
shown as strike-outs and underlines in
Sections 6.0 - 6.7 on
pages 1-41 of Chapter 6, Revision 5,
dated 12/06/96.

Systematic review of Chapter 6, Section
by Section, starting at 6.8 on page 41 of the
double-spaced Revision 4 of Chapter 6 dated
12/06/96. After going through Sections
6.8 and 6.9, we will have completed our
review of the entire Chapter.

Discuss “unconditional reciprocity,”
Section 6.2(c).

2:30 p.m. ± - Break

3:45 p.m.

- Assess progress made at today’s meeting.
- How to proceed from here.
- Do we need our next meeting currently
scheduled for 1:00 p.m. Eastern Standard
Time on Wednesday, December 18, 1996?

4:00 p.m. - Automatic Shutoff.